Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13021

0 - FRONT

MEDWATCH
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

Page CFSAN → ephedrine

Form Approved OMB No 0910-0291 Expires 12/31/94
See OMB statement on reverse

FDA Use Only
Triage unit sequence # 86691
13021

A. Patient information

1 Patient identifier	2 Age at time of event: 43 or Date of birth: [redacted]	3 Sex	4 Weight
[redacted] In confidence		☐ female ☑ male	160 lbs or ____ kgs

B. Adverse event or product problem

1 ☑ Adverse event and/or ☐ Product problem (e g , defects/malfunctions)

2 Outcomes attributed to adverse event (check all that apply)
- ☑ death 11-1-97 (mo/day/yr)
- ☐ life-threatening
- ☐ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other

3 Date of event (mo/day/yr) 11-1-97

4 Date of this report (mo/day/yr) 7-11-98

5 Describe event or problem

On Saturday, Nov. 1, [redacted] took his younger son to a [redacted] game in [redacted]. He had left home (in [redacted]) on Fri. night and was planning to return home Sat. night. He took his son to the ball game & returned to his mother's home. He & his sisters & mother went out to eat. They returned to his mom's house. He visited for awhile & then stood up to come home about 9:00 p.m. He walked to the back of the house & he fell. He was in full cardiac arrest. 911 was called, they worked on him & took him to [redacted], He never regained

6. Relevant tests/laboratory data, including dates

consciousness & was declared dead at 9:21 p.m. He had had no physical problems that day. Diagnosis - Acute myocardial infarction with sudden cardiac death. When ambulance arrived, he was in ventricular fibrillation / report available from [redacted]

7 Other relevant history, including preexisting medical conditions (e g , allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

-no preexisting medical problems there was a family history of heart problems but none had been identified for patient. heart murmur at birth, but it had been checked often & no prob. indicated deceased had never smoked or drank alcohol

C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler, if known)
- #1 Ripped Fuel Metabolic Enhancer
- #2 guarana Extract 910mg (per 2) Twin Laboratories Inc

2 Dose, frequency & route used	3 Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 2 before breakfast 6 tablets lunch & dinner daily	#1 April '97 –
#2	#2 Nov '97

4 Diagnosis for use (indication)
- #1 dietary supplement
- #2 to increase energy

5 Event abated after use stopped or dose reduced
- #1 ☐ yes ☐ no ☑ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

6 Lot # (if known)
- #1
- #2

7 Exp. date (if known)
- #1
- #2

8 Event reappeared after reintroduction
- #1 ☐ yes ☐ no ☐ doesn't apply
- # ☐ yes ☐ no ☐ doesn't apply

9 NDC # (for product problems only)
– –

10 Concomitant medical products and therapy dates (exclude treatment of event)

RECEIVED
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D. Suspect medical device

1 Brand name

2 Type of device

3 Manufacturer name & address

REC'D.
JUL 17 1998

4 Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other

5 Expiration date (mo/day/yr)

6
- model #
- catalog # MEDWATCH CTU
- serial #
- lot #
- other #

7 If implanted, give date (mo/day/yr)

8 If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ____ (mo/day/yr)

10 Concomitant medical products and therapy dates (exclude treatment of event)

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E. Reporter (see confidentiality section on back)

1 Name, address & phone #

[redacted] (wife)

2 Health professional?	3. Occupation	4 Also reported to
☐ yes ☑ no	tea	☑ manufacturer ☑ user facility ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☒

FDA Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93) 86691

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

ADVICE ABOUT VOLUNTARY REPORTING

Report experiences with:

- medications (drugs or biologics)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- other products regulated by FDA

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent impairment or damage

Report even if:

- you're not certain the product caused the event
- you don't have all the details

Report product problems – quality, performance or safety concerns such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labeling

How to report:

- just fill in the sections that apply to your report
- use section C for all products except medical devices
- attach additional blank pages if needed
- use a separate form for each patient
- report either to FDA or the manufacturer (or both)

Important numbers:

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-7737 to report by modem
- 1-800-FDA-1088 for more information or to report quality problems
- 1-800-822-7967 for a VAERS form for vaccines

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity may be shared with the manufacturer unless requested otherwise. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

FDA Form 3500-back **Please Use Address Provided Below – Just Fold In Thirds, Tape and Mail**

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Rockville, MD 20857

Official Business
Penalty for Private Use $300

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES OR APO/FPO

BUSINESS REPLY MAIL
FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE, MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

MEDWATCH
The FDA Medical Products Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787

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CLINICAL RESEARCH
& REVIEW/OSN HFS-45

7. History
- patient was 5'10 & weighed 160 pounds at death
- he was physically active - played ball, carried Coca Cola product on route daily
- patient had never taken illegal drugs & rarely took even an aspirin
- patient took Ripped Fuel as a vitamin.

86691

Adverse Reaction Questionnaire

Complaint Number: CFSAN PROJ. #13021 Investigator: KIMBERLY L. CUNNINGHAM

Consumer Information

Date of Report: AUG 4, 1998 (MM/DD/YY)

Initial Report Source: X ORA Consumer Injury
☐ Telephone ☐ Correspondence X MedWatch
☐ USP ☐ PQRS ☐ Poison Control ☐ CDC

Name: [redacted] Gender: ☐ F X M Age: 43

Race: X 1-White ☐ 2-Black ☐ 3-Asian/Pacific Islander ☐ 4-Native American ☐ 5-Hispanic
☐ 8-Other _____ ☐ 9-Unknown

Information on Adverse Reaction

Date of Adverse Reaction: NOV 1,1998
Previous Reaction to Product Type: ☐ Yes ☐ No N/A

Give the site of consumption/ingestion (e.g. home, restaurant, office):
Home

The following information relates to the consumer's use of the product.

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms):
On or about April 1997, victim started taking the product Ripped Fuel. The product was recommended to him by a [redacted] store manager for an increase in energy. Complainant assumes that the her husband followed the instructions on the bottle, and consumed at least 6 capsules a day 5 days a week. On June 9, 1997 the victim passed out while driving, and hit another car without being aware of it. It was reported that the victim urinated frequently, and was very irritable most of the time. There was a change in physical appearance such as bulking up of legs, chest, arms and weight loss. He continued taking the product throughout the summer. As the fall progressed, victim became an early morning person, and got very irritated at the family if they were not up early which was out of character for him. He would go to bed around 8:00 p.m. every night, and he was normally a night person according to complainant. On November 1, 1997, victim took his son to a football game in [redacted] After the football game, he and his son visited his mother in [redacted]. Around 8:55 p.m he was on his way to the restroom, and fell to the ground. The family called 911. Victim was taken to the hospital, and the EMT's tried to revive him for about an hour, but were not successful. The doctor that treated the victim explained to the victim's wife that his heart was fluttering and would not beat.

How long did the symptoms last? Symptoms lasted from June 97 to November 1, 1998 (time of death)
Give the circumstances of exposure (i.e. how much was taken, how was the product taken and how often was it taken, etc.).
2 tablets 3 times a day (6 tablets a day) April - November--Complainant was uncertain how much was taken during the day by her husband. There were a total of 120 capsules in the bottle, and approximately 1/4 of the product remained. Ms. [redacted] had thrown away the original bottle in February 1998 that her husband had taken, and recently purchased another bottle to be used for reporting adverse reaction to FDA.

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event:

Mr. [redacted] occasionally took bronchidialators for his asthma.
Week prior to death the victim was taking Axid (OTC).

Did event abate after use of suspected product stopped or dose reduced?: ☐ Yes ☐ No x Unknown
Did symptoms reoccur after reintroduction of suspected product?: ☐ Yes ☐ No ☐ Unknown x Not Applicable
Did symptoms reoccur after using other products with the same ingredients?: ☐ Yes ☐ No ☐ Unknown x Not Applicable

Medical Information

Was a Health Care Provider Seen?: ☐ Yes x No
Give Health Care Provider's name, address and telephone number:
Dr. [redacted]

Occupation of Health Care Provider: X MD ☐ Osteopath (DO) ☐ Naturopath ☐ Nurse ☐ Pharmacist
☐ Other (specify) _____

What medical tests were performed and what were the results?

No other medical tests were performed prior to his death.
What was the medical diagnosis? N/A
What treatment(s) was(were) given (e.g., drugs, other)?
N/A

Were there any preexisting condition(s)/treatment(s)? x Yes No
(If YES, list them including allergies and chronic diseases):
Asthma

Product Category

1. Adverse Reaction to:
   - ☐ **Medical Food** (under medical supervision) ☐ **Infant Formula**
   - x **Dietary Supplement** (a vitamin; an essential mineral; a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe; amino acids; extracts from animal glands; garlic extract; fish oils; oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin; and mixtures of these ingredients.)
   - ☐ **Other (traditional food)** _____

Other Product Problems

2. ☐ Foreign Object (specify): _____

_____

3. ☐ Other (specify): _____

Information on Suspected/Alleged Product

Give the product name as listed on the label (including the recommended dosage/serving size, recommended duration of use and indications for use as listed on the label):
"***TWINLAB METABOLIC ENHANCER RIPPED FUEL 120 Capsules*** ***RECOMMENDED USE: As a dietary supplement, take 2 capsules before morning workout on an empty stomach. Also, take 2 capsules before afternoon and evening meals. Do not exceed 6 capsules daily. Taking more than the recommended amount will not improve results and may cause adverse reactions listed in the warning below. Begin use with one-half the recommended dose (one capsule three times per day) to assess your tolerance. Improper use may be hazardous to a person's health. For best results, use as part of a low-fat diet and exercise program. The maximum recommended dosage of ephedrine for a health adult human is no more than 100 mg in a 24 hour period for not more than 12 weeks. Please not: Guarana extract contains caffeine and should not be taken by those wishing to eliminate caffeine from the diet.***" LABELING ATTACHED.

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):
☐ Check here if ingredients are unknown

MaHuang Extract (standardized 20 mg ephedra alkaloids-334 mg; Guarana Extract (standardized for 22% caffeine-910 mg;

L-Carnitine 100 mg; Chromium (for Chronic Fuel Patented Chromium Picolinate 200 mg.

If a particular ingredient is suspected of contributing to the reaction, please indicate the appropriate category below:

☐ Aspartame
☐ Monosodium Glutamate
☐ Sulfite
x Other EPHEDRA ALKALOIDS
☐ Unknown
☐ Color Additive (please specify) _____

Is the product label available (if yes submit a quality copy along with this questionnaire)? X Yes ☐ No ☐ Unknown
Product Sample Available?: X Yes ☐ No ☐ Unknown

Outcome Attributed to Adverse Event:
If yes, include pertinent medical records)

Death: X Yes ☐ No

Life-Threatening: X Yes ☐ No

Hospitalization: X Yes ☐ No (If YES, indicate if initial or prolonged) victim died at hospital.

Required Intervention to prevent permanent impairment/damage: x Yes ☐ No

Did the adverse reaction result in congenital anomaly: x Yes ☐ No

13021

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum
Food & Drug Administration
Nashville District

Date August 24, 1998

From Kimberly L. Cunningham/CSO/NSV-DO Kimberly L. Cunningham

Subject Follow-up on Adverse Event Report CFSAN Project #13021 Assignment #8-057

To CFSAN/DOEP, HFS-636 thru M. Anthony Abel,I/SCSO M Anthony Abel, I

Attached is the adverse reaction questionnaire, product labeling, and medical records for CFSAN project #13021, MedWatch #86691. Ms. [redacted] was interviewed at her home on 08/04/98, and the product "Ripped Fuel" was collected on 08/18/98, directly from Ms. [redacted] at her place of employment. Medical records were obtained from the victim's family physician, and the hospital where victim was taken to the ER after having heart attack. A sample (#25152) of Ripped Fuel collected from Ms. [redacted] was sent to [redacted] on 08/24/98 for analysis of ephedra alkaloids.

Attachments:
MedWatch assignment #8-057
Adverse Reaction Questionnaire
Medical Records from [redacted]
Medical Records from [redacted]